REMARKS

Applicants acknowledge the current status of the claims, as reported in Office Action dated 02 May 2006. Claims 1-13 are pending; and claims 1-13 are subject to restriction and/or election requirement. The Examiner has required restriction to one of two groups under 35 U.S.C. §121 as listed on page 2 of the instant Office Action.

Specifically, the Examiner has restricted the claims of the present application as follows:

I. Claims 1-11, drawn to a method of treating a subject suffering from anemia comprising administering a TNFα antibody; classified in Class 424, subclass 145.1.

II. Claims 12-13, drawn to a kit comprising a TNFα antibody; classified in Class 530, subclass 388.23.

The Examiner further requires election of species. The asserted species consist of:

(a) anemia related to rheumatoid arthritis

(b) anemia of infection and chronic inflammatory diseases

(c) iron deficiency anemia

(d) autoimmune hemolytic anemia

(e) myelophthisic anemia

(f) aplastic anemia

(g) hypoplastic anemia,

(h) pure red cell aplasia

(i) anemia associated with renal failure or endocrine disorders

(j) megaloblastic anemias

(k) defects in heme or globin synthesis

(l) sickle-cell anemia

(m) sideroblastic anemia

(n) anemia associated with chronic infections

Briefly, the reasons for restriction asserted in the Office Action are that Invention I is drawn to a process of use, and Invention II is drawn to a product, which product can be used in a materially different process. Applicants respectfully traverse the restriction of claims, and request reconsideration and withdrawal of restriction requirement.

Proper restriction between independent and distinct inventions claimed in the same application requires that (1) the invention must be independent and distinct as claimed and (2) there must be a

serious burden placed on the Examiner by not requiring election. If either criteria are not met, restriction is not proper. The term "independent" means that there is no disclosed relationship between the two or more subjects disclosed in a patent application. The term "distinct", means two or more subjects as disclosed are related but are capable of separate manufacture, use or sale as claimed, and are patentable over each other. (see M.P.E.P. §802.01). Further, with respect to the burden of the examination, M.P.E.P. §803 states in relevant part, "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions."

Applicants assert that the claims are drawn to a single inventive concept and a single inventive effort, the search and examination of which would not place a serious burden on the Examiner. The claims are different aspects and embodiments of the same disclosed subject matter.

Applicants' invention is directed to a method of treating anemia in a subject comprising administering to a subject in need, a therapeutically effective amount of a TNFα antibody, wherein the antibody dissociates from human TNFα with a K_d of 1 x 10^{-8} M or less and a K_{off} rate constant of 1 x 10^{-3} s^{-1} or less, such that anemia is treated. Additional embodiments of the invention include the product, a kit comprising a pharmaceutical composition comprising the TNFα antibody to be administered to a subject being treated for anemia. Thus, the method of treating anemia in a subject with a therapeutically effective amount of a TNFα antibody, and the kit comprising a pharmaceutical composition comprising the TNFα antibody are both linked. Therefore, the subject matter of Applicants' Patent application are not "independent" as determined by M.P.E.P. 802.01.

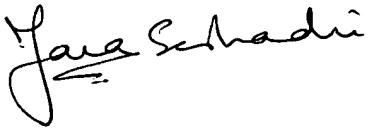
The pharmaceutical composition comprising the TNFα antibody in the kit is to be used to treat anemia in the subject. Thus, the method of treating anemia in a subject, and the kit comprising a pharmaceutical composition comprising the TNFα antibody represent different embodiments of one invention. Therefore, the subjects disclosed in the instant application do not meet the criteria for "distinct" as defined in M.P.E.P. § 802.01.

The present application contains a single searchable, unifying aspect, i.e. method of treating anemia in a subject with a TNFα antibody, and a kit that comprises a TNFα antibody to treat anemia in a subject. Therefore, Applicants submit that the Examiner can search and examine the application without serious burden. Thus, Applicants respectfully submit that Applicants' invention does not meet the threshold of "two or more independent and distinct" inventions as required in 35 U.S.C. §121 and as such the restriction requirement is improper. In view of the foregoing, Applicants respectfully request withdrawal of the restriction requirement.

Notwithstanding Applicants' belief that the restriction and requirement of election are improper, and without in any way acquiescing to the reasons for the requirements set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicants provisionally elect for examination the claims of Group I.

As to election of a species, Applicants elect the disclosed species (a) anemia related to rheumatoid arthritis. It is Applicants' understanding that the species election is for searching purposes only and, upon a finding of allowability of the elected species, the remaining species also will be searched. Applicants also reserve the right to traverse the restriction between the non-elected groups and species in this or a separate application.

Respectfully submitted,



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